REMARKS

Claims 1-42 are pending in the application prior to entry of this amendment. Claims 1, 3-6, 9-11, 17-19, 22-24, 29, 37, 39 and 41 are being amended and Claims 43 and 44 are being added.

In the April 11, 2003 Office Action, the Examiner rejected Claims 1-28 and 37-42 under 35 USC §102(e) as being anticipated by U.S. Patent 6,480,733 to Turcott ("Turcott"). As set forth below, all the claims are believed to be allowable as presented and therefore, this rejection is respectfully traversed. The noted claims include four Independent Claim sets (Claims 1, 17, 22 and 37).

Independent Claims 1 and 37 are directed to monitoring a Mayer wave effect. As will be appreciated, obtaining physiological parameter information related to the Mayer wave requires distinguishing effects in the pleth signal cased by the Mayer wave from other effects, e.g., caused by a patient's respiration. This raises certain difficulties in view of the fact that some of these components (e.g., respiration) can occur within overlapping frequency ranges. However, it has been recognized that the spectral composition of the Mayer wave can be readily characterized and conveniently analyzed. That is, by transforming a time-based pleth signal into a frequency domain signal (i.e., into spectral information), the effects of the Mayer wave are more readily isolated. Furthermore, it will be appreciated that pleth signals are susceptible to noise (e.g., motion artifact, light interference, electrical interference) that can make it difficult to extract information from a time-based signal. In any case, transformation of the time-based pleth into a frequency domain signal allows for more readily isolating effects (e.g., for monitoring purposes) associated with the

Mayer wave from other effects. Accordingly, each of Independent Claims 1 and 37 utilizes a frequency based analysis of a time-based pleth signal to better isolate Mayer wave effects.

The method of Claim 1 involves obtaining a time-based pleth signal that is modulated based on interaction of transmitted optical signals with a patient's blood. This time-based pleth signal is transformed into a frequency domain in order to obtain spectral information including at least first information associated with a fundamental frequency of the pleth. Once the pleth signal is transformed, the resulting spectral information may be further processed to identify effects (i.e., physiological parameter information) related to the Mayer wave. For example, once transformed into spectral information, the Mayer wave component of that signal may be readily identified through frequency-based filtering. Accordingly, an output related to the identified Mayer wave effect is provided.

Independent Claim 37 provides an apparatus that is operable to transform a time-based pleth signal into a frequency-based spectral information signal for use in identifying Mayer wave effects. As will be appreciated, the ability to perform this transform enables the apparatus to provide spectral analysis of a pleth signal and thereby more readily separate the effects of respiration from the effects of the Mayer wave in a pleth signal.

Turcott utilizes fundamentally different structure/methodology than that discussed above. In particular, Turcott fails to disclose or suggest the use of spectral analysis (i.e., transforming a time-based pleth into a frequency domain for analysis) for monitoring a Mayer Wave effect. Rather, Turcott discloses monitoring a time-based plethysmographic signal to identify the presence of fluctuations in pulse amplitude that are caused by respiration and the Mayer wave. In this regard, Turcott notes that the presence of respiratory fluctuations may be tested in a frequency the range of

0.17 Hz to 0.4 Hz and the presence of Mayer waves may be tested in a frequency range of 0.03 Hz to 0.1 Hz. Furthermore, Turcott discusses band pass filtering a time-based pleth signal to isolate variability over these specific frequency ranges. Turcott notes, the absence of fluctuation in these frequency bands may suggests that a disease (i.e., heart failure exacerbation) is worsening. Turcott simply discloses determining whether fluctuations exist within a predetermined frequency band of a time-based pleth signal. Turcott does not perform spectral analysis of a frequency based signal or provide an output associated with the Mayer wave. Accordingly, Applicant request that this rejection be withdrawn.

Independent Claim 17 provides a method for monitoring low frequency blood volume variations within a patient. The method includes obtaining a time-based pleth signal and transforming that signal into a frequency domain in order to obtain a spectral information signal. This spectral information signal will include at least a first peak associated with a fundamental frequency of the pleth, which will typically be associated with the heart rate of the patient. Based on this fundamental frequency, the spectral information signal is further processed to obtain information regarding a low frequency blood volume variation of the patient that relates to a second peak of the spectral information signal. This second peak may be located in a frequency band between about 0.05 Hz and 0.5 Hz. Accordingly, this low frequency blood volume variation may be monitored over time to identify a characteristic of interest. In this regard, an amplitude and/or frequency of the low frequency blood volume variation may be monitored.

Independent Claim 22 provides a method for monitoring low frequency heart rate variability of a patient. In this regard, a time-based pleth signal is obtained for a patient. A Fourier transformation is performed on the time-based pleth signal to transform the time-based pleth into a

spectral information signal in a frequency domain. This spectral information signal is then processed to obtain heart rate information which may in turn be processed to obtain information regarding heart rate variability. The heart rate variability information may be monitored to identify a characteristic of interest therein. In one particular embodiment, the step of first processing comprises obtaining a time series of heart rate values from the spectral information signal to provide the time series of heart rate values. In this regard, the method provides for transforming the time-based signal into a frequency-based signal and plotting one or more components of the frequency-based signal back into the time domain. This allows for trending effects that have been isolated from a pleth signal through spectral analysis.

Turcott fails to disclose or suggest transforming a time-based pleth into a frequency domain in order to obtain spectral information. Accordingly, Turcott fails to disclose or suggest use of sprectral information in determining, inter alia, fundamental frequencies, heart rate variability and/or blood volume variability. Rather, Turcott utilizes time-based vascular plethysmography signals to measure changes in pulse amplitudes and/or pulse amplitude variability, which are considered to be indicative of heart failure exacerbation. See Abstract. Turcott utilizes a threshold crossing method to identify a pulse rate from a plethysmographic signal and determines maximum and minimum pulse amplitudes for each pulse cycle. See column 20, lines 24-26. An average of these pulse cycles is calculated and compared with previously stored values to identify variations, which Turcott considers to be indicative of heart failure exacerbation. Turcott discloses determining whether variations exist within a time-based pleth signal. Turcott does not generate a spectral information signal or perform analysis of such a signal for monitoring purposes. Accordingly, Applicant request that this rejection be withdrawn.

The Examiner also rejected claims 29-36 under 35 USC §103(a) as being unpatentable over Tucott in view of U.S. Patent 6,099,481 to Daniels et al. ("Daniels") and further in view of U.S. Patent 4,813,427 to Schlaefke et al. ("Schlaefke"). This rejection is respectfully traversed.

Independent Claim 29 provides a method for monitoring effects related to the Mayer wave in a plethysmographic signal where Mayer wave effects can be effectively isolated from respiration effects that may sometimes occur in overlapping frequency ranges. In this regard, a photoplethysmographic instrument is configured for pleth analysis of a patient. The respiration of the patient is caused to be at least a given threshold (e.g., elevated). This threshold respiration rate has a frequency greater than a frequency range associated with the Mayer wave. Accordingly, a pleth signal is obtained while the respiration rate is maintained at or above the threshold. The pleth signal may then be processed to identify an effect related to the Mayer wave. As will be appreciated, since the effect of respiration on the pleth is in a frequency range isolated from the frequency range of the Mayer wave, simple band pass filtering may be utilized to identify and output the Mayer wave effects. That is, by controllably elevating the patient's respiration rate above a frequency range associated with the Mayer wave, Mayer wave effects may be effectively isolated without the spectral analysis discussed above.

Turcott fails to recognize that the Mayer wave and respiration may occur in an overlapping frequency range. Accordingly, Turcott fails to disclose or suggest elevating the respiration rate of a patient to a frequency outside of a frequency range associated with the Mayer wave. Neither Daniels nor Schlaefke recognize the existence of the Mayer wave let alone elevating a patient's respiration frequency to be outside of a frequency range associated with the Mayer wave such that effects of the Mayer wave may be isolated within a pleth signal. Accordingly, Applicant submits that the

combination suggested by the Examiner fails to obviate the subject matter claimed in Claim 29. Applicant respectfully requests that this rejection be withdrawn.

Based upon the foregoing, Applicants believe that all pending claims are in condition for allowance and such disposition is respectfully requested. In the event that a telephone conversation would further prosecution and/or expedite allowance, the Examiner is invited to contact the undersigned.

Respectfully submitted,

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